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10/576,372

04/19/2006

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EXAMINER

DANG, IAN D

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

04/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/576,372 | <b>Applicant(s)</b><br>ROSSI ET AL. |  |
|                              | <b>Examiner</b><br>IAN DANG          | <b>Art Unit</b><br>1647             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-45 is/are pending in the application.
- 4a) Of the above claim(s) 26-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-25 and 32-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 09 January 2008 has been entered in full. Claims 1-21 have been cancelled and claims 22, 24-25, 32, and 44 have been amended. Claims 26-31 have been withdrawn as drawn to a non-elected invention.

Claims 22-25 and 32-45 are under examination.

### ***Claim Objections***

The objection made to claim 22 has been withdrawn in view of the amendments made to claim 22.

### ***35 USC § 112, Second paragraph***

Applicant's response, arguments, amendments made to claims 32 and 44 filed on 01/09/2008 have overcome the rejections of claims 22-25, 32-42, and 44-45 under 35 USC 112, 2<sup>nd</sup> paragraph. The rejections of claims 22-25, 32-42, and 44-45 under 35 USC 112, 2<sup>nd</sup> paragraph have been withdrawn.

Applicants' amendment of the claims with the term "eluate" or the phrase "selected from urine or cell culture supernatant" have overcome the rejection under 35 USC 112, 2<sup>nd</sup> paragraph regarding the term "fluid".

Applicants' amendments made to claim 32 have clarified how the limitations of claim 32 relate to claim 22. In view of these amendments, Applicants have overcome the rejection of claims 32, 34, and 36 under 35 USC 112, 2<sup>nd</sup> paragraph.

Applicants' amendments made to claims 44 and 45 have clarified how the limitations of claims 44 and 45 relate to claim 22. In view of these amendments, Applicants have overcome the rejection of

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claims 44 and 45 under 35 USC 112, 2<sup>nd</sup> paragraph.

Applicants argument that the phrase “strong anion exchange chromatography” is defined in the specification at page 2, lines 9-12 have overcome the rejection under 35 USC 112, 2<sup>nd</sup> paragraph regarding the term “strong anion exchange chromatography”.

***35 USC § 112, First paragraph (written description)***

Applicant’s response and arguments filed on 01/09/2008 have overcome the rejection of claims 22-25, 27, 28, 32-45 under 35 USC 112, 1<sup>st</sup> paragraph. The rejection of claims 22-25, 27, 28, 32-45 under 35 USC 112, 1<sup>st</sup> paragraph has been withdrawn.

**Rejection Maintained**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors.

In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 22-25, 38, 39, 42, 43, and 44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti E. (2002, TRENDS in Biotechnology, Volume 20, Issue 8, pages 333-337) in view of Xiang et al. (2001, The Journal of Biological Chemistry, Volume 276, Issue 20, pages 17380-17386) for the reasons already of record on page 8-10 of the office action mailed 10/09/2007.

At page 9 of the response, Applicants note that the cited reference does not teach that this segment of the mature IL-18BP is an Ig domain; rather, 60% of human IL-18BP resembles an Ig domain. Further, the cited reference indicates that the predicted Ig domain of IL-18BP has only about 25% amino acid sequence identity with a similar domain within the IL-1 receptor (page 17380, column 2, first full paragraph) and provides no teaching as to the degree of similarity the IL-18BP has with immunoglobulin molecules or domains thereof.

Applicants' arguments are not persuasive. Although IL-18BP and IL-1 receptor have limited resemblance to an antibody or an IgG, the specification teaches that this technique is widely employed for proteins in general and does not appear to be limited to antibodies. For instance at page 2, line 20, of the specification, Applicants recite that chromatographic systems having a hydrophobic stationary phase have also been widely employed in the purification of proteins and included in this category are hydrophobic interaction chromatography (HIC) and reversed phase liquid chromatography (RPLC). Since IL-18BP is a protein, it would be obvious for one skilled in the art to use the hydrophobic charge induction chromatography purification process as taught by Boschetti E. (2002) for the purification of IL-18BP.

Under *KSR*, it's now apparent "obvious to try" may be an appropriate test in more situations than we previously contemplated. When there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try may show that it was obvious under § 103 (*KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, \_\_\_, 82 USPQ2d 1385, 1397 (2007)).

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Therefore, in view of KSR and in combination with the fact hydrophobic charge induction chromatography (HCIC) represents an improvement towards achieving the ideal situation in the design of an antibody-selective sorbent and the operating characteristics of the sorbents permits significant process simplification compared with traditional approaches, and also a good level of specificity (Boschetti et al., 2002, page 333, right column 2<sup>nd</sup> full paragraph), it would be reasonable to use the method of Boschetti et al., (2002) for the purification of IL-18BP.

In addition, Applicants also note that the IL-1 receptor is not an immunoglobulin. Further, the purification noted in the Office Action relates to the use of avidin/biotin affinity chromatography to purify biotinylated polypeptides. Such purification relies upon the affinity of biotin for avidin/streptavidin for the purification process (see page 13381, paragraph bridging columns 1-2) and is a process significantly different from that taught in Boschetti and recited within the instant claims.

Applicants' arguments are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, the reference by Xiang et al. discloses that IL-18BP has structural characteristics that are similar to an immunoglobulin IgG by reciting "that approximately 60% of the mature human IL-18BP resembles an immunoglobulin (IgG) domain that includes a highly conserved pair of cysteines and tryptophan residues" and by comparing it to another protein with similarities to immunoglobulin such as only about 25% amino acid sequence identity with a similar domain within the IL-1 receptor. Xiang et al. recite that the resemblance to IL-18BP is appropriate because IL-18 itself is not an immunoglobulin because. The structural similarities of IL-18BP to an IgG disclosed by Xiang et al. can be utilized to purify it with methods used for the purification of immunoglobulin.

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Finally, the examiner agrees with Applicants that the IL-1 receptor is not immunoglobulin and that the purification of IL-18BP relies on affinity of biotin for avidin/streptavidin for the purification process. However, the Examiner's interpretation of Xiang et al. indicates that portion of the IL-1 receptor has structural features of an immunoglobulin and that Xiang et al disclose a method for the purification of IL-18BP.

At page 9 of the response, Applicants argue that one skilled in the art would not have been motivated to combine the cited references to arrive at the claimed invention nor would one skilled in the art have had a reasonable expectation of success in applying HCIC to the purification of IL- 18BP (particularly in view of the teachings that only about 60% of the mature form of human IL-18BP resembles an immunoglobulin domain and that this segment of IL- 18BP only has about 25% sequence identity to human IL 1 receptor).

Applicant's arguments have been fully considered but are not found persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of skill in the art would have been able to modify the method of purification of IL-18BP because the hydrophobic charge induction chromatography (HCIC) represents an improvement towards achieving the ideal situation in the design of an antibody-selective sorbent. Since one skilled in the art would have expected success because IL-18BP has structural features similar to that of an immunoglobulin and methods of purifying antibodies with HCIC were successful in the art.

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### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
April 22, 2008

/Robert Landsman/  
Primary Examiner, Art Unit 1647